

### **REMARKS**

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

#### **I. Claim Amendments**

Claims 1-5, 7-22, 24-53, 56 and 57 are requested to be cancelled. Applicants reserve the right to prosecute the subject matter of the cancelled claims in this or another application.

Claim 55 is currently being amended.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

It is acknowledged that the foregoing amendments to the claims are submitted after final rejection. However, because the amendments do not introduce new matter, and either place the claims in condition for allowance or at least in better condition for appeal, entry thereof by the Examiner is respectfully requested.

After amending the claims as set forth above, claims 1-5, 7-22, 24, 26-53, and 55-58 are now pending. Thus, claims 55 and 58 are pending and being examined on the merits.

#### **II. Election/Restriction**

The examiner noted that the restriction requirement is still considered proper and final. Accordingly, the examiner has withdrawn all claims but claims 55-58 drawn to HARL. Applicants traverse the restriction requirement for the reasons already of record.

#### **III. Double Patent Rejections**

Claims 55-58 stand provisionally rejected under the doctrine of obviousness-type double patenting over claims 11 and 12 of Application No. 10/146,130. Applicants

respectfully request that the Examiner hold this rejection in abeyance until allowable subject matter is indicated in one of the applications.

#### **IV. Claim Rejections – 35 U.S.C. § 112**

Claims 55-58 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically, the specification allegedly does not denote a “HARL” core sequence but only denotes longer core sequences that contain “HARL.” In addition, the claim elements allegedly have been arranged in such a way as to “define a new sub-genus not supported by the specification as originally filed.” Office action at 5-6. Applicants respectfully traverse this ground of rejection.

##### **A. HARL Core Sequence**

Contrary to the examiner’s statement, the specification does demonstrate possession of the HARL core sequence. The examiner cites “THARLIL,” “HHARLCL,” “MFARLIL,” “HHARLIF,” and “HARLML” to support her position that the HARL core sequence is not supported by the specification. However, all but one of these sequences has a common motif – HARL. The written description requirement is not an *in haec verba* requirement but instead is meant to require patent applicants to demonstrate possession of the claimed invention. *See* MPEP 2163(I)(B). The claims can be supported by express, implicit, or inherent disclosure. *Id.* In this case, Applicants clearly demonstrated possession of the HARL core sequence by listing a number of sequences having the HARL sequence as a common motif.

Even if the written description requirement did require an *ipsis verbis* recitation of claimed subject matter, the present specification as-filed satisfies this standard, as well. Specifically, original claim 1 recited “HARL” as a core sequence. *See* original claim 1(b); *see also* original claims 6, 23(b), 25(b). “The claims as filed in the original specification are part of the disclosure....” MPEP 2163(I)(B). (*citing In re Benno*, 768 F.2d 1340 (Fed. Cir. 1985)). Thus, the HARL core sequence has literal support in the specification as-filed.

**B. Combination of Elements**

The examiner further alleges that the specific combination of claim elements constitutes a “sub-genus not supported by the specification as originally filed.” Office Action at 5-6. However, the specification does in fact support the specific subject matter claimed. As noted above in Section III(a), the specification supports the core sequence HARL. In addition, the specification discloses that the peptides containing the HARL sequence are no longer than 25 amino acids and that these additional amino acids may be part of an NTP sequence. *See* page 9, ll. 4-7, 13-15. The originally filed claims further support this understanding by claiming this specific combination. *See* original claim 6. Thus, the specification fully supports claim 55.

Claims 56-58 contain the additional recitation “said peptide binds to a NTP,” which is also supported by the specification as-filed. The specification contains numerous statements that the invention provides NTP “binding partners.” *See, e.g.*, page 5, ll. 14-17, 21-23; page 10, ll. 2-5. In fact, the claimed invention is based in part on the discover that “the Harlil peptides have unique binding characteristics.” *See* page 5, ll. 19-20. Specifically, the peptides disclosed “have an affinity to bind to NTP.” *See* page 5, l. 21. In addition, original claim 28 discloses a method wherein the peptides presently claimed inherently bind to NTP. Thus, the as-filed specification supports the recitation that the claimed sequences bind to NTP.

In summary, the specification as-filed demonstrates possession of the claimed invention. Accordingly, Applicants respectfully request reconsideration and withdrawal of this ground of rejection against claim 55-58 under 35 U.S.C. § 112, first paragraph.

**V. Claim Rejections – 35 U.S.C. § 102**

While not acquiescing in the examiner’s rejections, claims 56 and 57 have been cancelled. Thus, the rejections under 35 U.S.C. § 102 are addressed below with respect to remaining claims 55 and 58.

**A. U.S. Patent No. 5,834,287 to Kubota *et al.***

Claims 55-58 stand rejected under 35 U.S.C. §§ 102(e) and (b) as allegedly anticipated by U.S. Patent No. 5,834,287 to Kubota *et al.* ("Kubota") as further evidenced by U.S. Patent No. 5,830,670 to de la Monte *et al.* The examiner cites Kubota's SEQ ID NO: 8, because it contains 17 amino acids and contains the HARL sequence. The examiner claims SEQ ID NO: 8 satisfies the recitation of claims 56(b) and 58(b), because the amino acids of SEQ ID NO: 8 occur somewhere in the NTP sequence. In other words, the examiner alleges that "[t]he claim does not require that the amino acids bear any particular homology to any particular portion of the neural thread protein sequence but merely require that they may be found in the full length sequence." Office Action at 7. Applicants respectfully traverse this ground of rejection.

While the claims do not require a particular degree of homology, the claims, as amended, do require that the peptides be able to bind to an NTP protein. Kubota does not relate to NTP but instead discloses enzymes that release trehalose from certain non-reducing saccharides. There is no teaching or suggestion that Kubota's SEQ ID NO: 8 binds to NTP. Accordingly, Kubota fails to teach each and every limitation of the claimed peptides. Accordingly, withdrawal of this ground for rejection is respectfully requested.

**B. Published PCT Application WO 00/55199 by Rosen *et al.***

Claims 56-58 stand rejected under 35 U.S.C. § 102(a) as allegedly anticipated by PCT Published Application WO 00/55199 to Rosen *et al.* ("Rosen"). Applicants respectfully traverse this ground of rejection.

Rosen discloses a secreted protein sequence 17 amino acids long that contains the sequence HA, but it does not contain the HARL sequence, as required by claim 58. Thus, Rosen does not anticipate claims 55 or 58. Accordingly, withdrawal of this ground for rejection is respectfully requested.

**C. U.S. Patent No. 6,610,506 by Lo *et al.***

Claims 56-58 stand rejected under 35 U.S.C. § 102(e) as allegedly anticipated by U.S. Patent No. 6,610,506 to Lo *et al.* ("Lo") as further evidenced by U.S. Patent No. 5,830,670 to de la Monte *et al.* Applicants respectfully traverse this ground of rejection.

Lo discloses a transferrin protein 17 amino acids long, which is cited by the examiner as a homolog of HARL "with the H deleted and the RL substituted attached to additional sequences of the neural thread protein...." Office Action at 9. However, Lo does not disclose the sequence HARL as required by claims 55 and 58. Accordingly, withdrawal of this ground for rejection is respectfully requested.

**D. U.S. Patent No. 5,830,670 by de la Monte *et al.***

Claims 57-58 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,830,670 to de la Monte *et al.* ("de la Monte"). Applicants respectfully traverse this ground of rejection.

de la Monte discloses a number of neural thread proteins, including SEQ ID NO: 120 cited by the examiner. SEQ ID NO: 120 is 375 amino acids long. *See* cols. 121-122. Thus, it is not "a peptide that does not exceed 25 amino acids," as required by claim 58. Accordingly, de la Monte does not anticipate claim 58. As such, withdrawal of this ground for rejection is respectfully requested.

**Conclusion**

The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

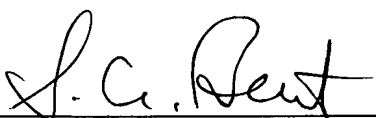
The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a

check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date 4 April 2005

By 

FOLEY & LARDNER LLP  
Washington Harbour  
3000 K Street, N.W., Suite 500  
Washington, D.C. 20007-5143  
Telephone: (202) 672-5538  
Facsimile: (202) 672-5399

*for* Michele M. Simkin  
Attorney for Applicant  
Registration No. 34,717